Living Well Together Randomized Controlled Trial – General Protocol

Updated January 1, 2019

1. Community Partnership

This RCT is the result of well-established community-based partnership in a medium-sized city (population 600,000) that had over three years working together prior to applying for the RCT's funding, with multiple involved agencies collaborating on other projects for even more years. The partnership included representatives from a university, a community health center, a religious organization providing supplies to food pantries, a non-profit focused on financial security for families, university extension services, and physical activity programing for youth and adults. Prior to the RCT, this group designed, obtained funding for, and implemented the pilot on which this RCT is based. A steering committee, called the Living Well Together Partnership, comprised of representatives from all partner organizations, meets quarterly and corresponds by phone and email throughout the duration of the RCT.

2. RCT

This RCT involves two arms, Education Only group (control) and the Health Coach group (intervention). Participants in the Education Only group receive educational materials on health family diet and activity (We Can booklets) and quarterly newsletters. In addition, they receive resource screenings at baseline and 6-months, follow-up phone calls using the Community Resource Specialist's screening questionnaire, and referrals to appropriate basic-needs resources.

Those in the Health Coach group received guidance from an assigned Health Coach, in which up to 5 in-person visits and 4 phone visits were completed within a 12-month period. MI was used during these sessions to help set goals based on the family's health needs and priorities. The Health Coach group participants received the same resource screening and newsletters as the Education Only group, but they also received additional resources to help their family's needs based on their goals made with the Health Coach.

Primary outcomes based on the 12-month intervention are separated by Index Adult and Index Child. For the Index Adult the primary outcomes are changes from baseline to 12-months in 1) BMI (kg/m^2), 2) the average minutes of moderate to vigorous activity, and 3) average hours of sedentary time per day. For the Index Child the primary outcomes are change from baseline to 12-months on sedentary time and minutes of moderate to vigorous activity per day and score on the Family Nutrition and Physical Activity tool (FNPA). In comparison to the Education Only group, we hypothesized that at 6, 12, and 18 months, families participating in the Health Coach group will demonstrate 1) a reduction in BMI for Index Adults, 2) an increase in minutes of moderate to vigorous physical activity and a decrease in sedentary time for both Index Adults and Index Children as measured by an accelerometer, and 3) a reduction in the number of obesity risk behaviors and an increase in the number of obesity prevention behaviors among Index Children as measured by the FNPA scale.

3. Participants

3.1. Inclusion and exclusion criteria

Index Adult and Index Child dyads were enrolled in the RCT if they met the following inclusion criteria: 1) Index Adult was 18 years or older; 2) Index Adult was not pregnant at the time of enrollment; 3) Index Adult was a parent or guardian of a child who was between the ages of 6 and 12 years old; 4)

Index Child was living with parent/guardian at least 5 out of the 7 days on average (80% of the time); 5) Index Adult must have lived within the county or the Index Child must attend the local public schools 6) Index Adult must have had a BMI of 30 or above (clinically obese); 7) Index Adult must have been able to converse in English or Spanish; 8) Index Adult and Index Child could not have been on specific medications that are associated with weight gain or loss or have certain medical conditions that would make it difficult for them to participate (exceptions were made for certain medications if participants' weight had been stable on that medication of more than 3 months); and 9) Index Adult must not have had significant physical limitations to exercise (must be able to at least walk the equivalent of one city block with an assistive device).

Other individuals in the family were involved with the intervention, such as the Primary Food Preparers (PFPs) and other children in the household ages 2 to 18 (Non-Index Children). These individuals were not subject to any inclusion/exclusion criteria; however, it was preferred they have the ability to converse in English or Spanish. There was no inclusion or exclusion criteria for household income. Individuals who previously participated in the pilot study and individuals from the same household were not eligible to participate. Families that did not meet these criteria were not enrolled but encouraged to contact research staff if their eligibility conditions changed.

4. Recruitment/randomization scheme, phone screening

Recruitment for the RCT occurred for 28 months on a rolling basis. To accommodate the varied background of participants, intervention materials were provided in English and Spanish (our target population). Though eligibility criteria did not include income recruitment sites were chosen to primarily target low-income families.

The two primary, and most successful, recruitment sites for enrolled participants were unemployment seminars and food pantries, both brick-and-mortar and mobile locations. At these seminars a clip board was circulated through the audience and interested persons could leave their name and contact information in order to complete a screening via phone at a later time. Research staff were also available after the seminars to answer any questions. At food pantry sites, intervention staff recruited in-person for four days a month, with a rotating schedule between the four largest pantries within the pantry network. Interested individuals were asked to fill out and return a "Consent to Contact" form to intervention staff at the recruitment tables. A scale was provided in a private area for interested individuals to weigh themselves to see about preliminary eligibility if their weight was unknown.

Similar recruitment strategies were completed at community or school events which catered to large numbers of low-income families. Monday Mail Folders, or similar systems, within elementary schools allowed flyers to be distributed to children within the district, who attend schools with high numbers of free and reduced lunch recipients. At the non-profit center focused on financial security for families, the Community Resource Specialist was housed and provided on-site recruit of participants seeking the center's assistance. All organizations at the center had intervention brochures and referred clients to the Community Resource Specialist, which may have contributed to some of the participants actively seeking participation in the study. Promotional materials were available in the waiting areas at other community partner locations. Healthcare providers (e.g., physicians, physician assistants, nurses or outreach workers) were used to reach eligible adult patients at the community health center. They provided these adults with intervention information and obtained contact information for interested families so that intervention staff could provide more information. Posters and brochures in the clinic encouraged adults with children to contact the intervention for information. This did not prove to be a

primary recruitment strategy, which was attributed to lack of communication between clinicians and intervention staff and priorities within the clinic for patient care over research.

Individuals that were recruited or who filled out a "Consent to Contact" form were contacted by research study staff to complete a phone eligibility screening. The phone screener went through the list of eligibility questions with the potential participant, and individuals were excluded if not meeting study criteria. Individuals who met study criteria provided contact and demographic information on an intake form, and the Index Child for the family was chosen via a computer randomization program from all eligible 6 to 12-year-old children within the household, if there were multiple children within this age range. The family was scheduled to meet with a Data Collector at their home or a participant-chosen community location (i.e. a private conference room at the library or at the community health center).

5. Data collection visits

Data Collectors reviewed informed consent documents and obtained written consent of the Index Adult for themself and their child and written assent of the Index Child at the time of the baseline interview. There were two Index Child assent forms used based upon the age of the child (ages 6-9 and ages 10-12) to align with standard reading comprehension levels. When the family included a Primary Food Preparer different than the Index Adult another written consent was obtained. All Non-Index Children (children ages 2 to 18 that resided within the household) were listed on another consent form in which the Index Adult could consent to them having limited participation in the study.

Data is collected on primary and secondary outcome measures at baseline, 6-month, 12-months, and 18-months. Data collection includes the Index Adult, the Primary Food Preparer (if different than the Index Adult), and the Index Child plus limited data on other Non-Index Children. Data Collectors collect height, weight, waist circumference, blood pressure measures, and questionnaire data on the Index Adults and the Primary Food Preparer. The Index Adults also answer questionnaires regarding the Index Child. Height and weight measures are collected for the Index Child, and the same measures are taken for the Non-Index Children if they wished to participate. At baseline and 12-month visits, the Index Adult and the Index Child are fitted with accelerometers to measure physical activity. 7 to 10 days later the Data Collector calls the Index Adult to complete a one-week recall for themselves regarding physical activity, and the Index Child also completes a one-week recall if they are between the ages of 10-12. The accelerometers are then returned for data processing via mail or picked up in-person by the Data Collector. If there is not a minimum of 5 days of wear-time to analyze, the Index Adult and/or the Index Child may be asked to wear the accelerometers for additional days to make up for the lost days.

6. Community Resource Mobilization, Randomization

Prior to randomization into intervention or control arms, the Community Resource Specialist met with enrolled families in-person or by phone and systematically screened them for basic needs (appendix- screener documentation form) and referred families to community resources to meet identified needs. These needs would otherwise present barriers to overall health. The Community Resource Specialist also assisted the Health Coaches in mobilizing resources for families. This study staff member was a community college employee who performed a similar function for the college and the resource center for working families. Health coaches followed-up with families to gauge resource utilization and encourage appropriate use, and also connected them to specific resources linked to their goal attainment. Direct contact from the Community Resource Specialist was utilized for families to facilitate this attainment. Types of resources included education, diet, exercise, and financial and other support.

Families were stratified (by recruitment site and self-identified race/ethnicity of the Index Adult) and randomized to the Health Coach group or the Education Only group in a 1:1 ratio by the Community Resource Specialist. A computer algorithm was used to randomize the families, and the Community Resource Specialist then discussed the results with the family and schedule the next step. Thus, Data Collectors were blinded to group assignment.

7. Study Conditions

7.1. Intervention (Health Coach group)

Participants in the intervention group were assigned a Health Coach by the Community Resource Specialist based on preferred language (English or Spanish) and Health Coach workload. The initial Health Coach visit was scheduled by the Community Resource Specialist for continuity of visits, allowing active engagement to continue throughout all portions of the study. The Health Coach guided families through a process to choose realistic meaningful goals for change using motivational interviewing and utilizing SMART framework for making goals. First, the coach and the family explored current behaviors, values, ambivalence toward change, and perceptions of family members' ability to change. Then, they discussed improvements the family wanted to make in diet, physical activity or other related items (such as sleep), motivations for change, and goals. Each family member was given a chance to suggest goals, and the Health Coach helped them set realistic goals. The family chose one or two goals and specific actions to achieve those goals. Family members were asked to gauge how important the stated goals were and how achievable the actions seem. If family members perceived the goals or actions to be unimportant or unachievable, the goals may have been revised until the majority agreed or the parents made a final decision. Family members signed an action plan listing the goal and steps to achieve it. For families who had difficulty identifying goals, the Health Coach assisted them in developing a menu of options to consider or their goal could be to continue the discussion with family about current behaviors, values and thoughts regarding change. As the family achieved the initial goals, the Health Coach encouraged them to set additional goals, including both diet and physical activity. Families were encouraged to share their goals with health care providers, family, and friends to gain support. The Health Coach and the family discussed resources needed to achieve these goals (e.g. equipment, information), and this information guided resource referrals.

Families were scheduled to meet with their Health Coach in their home or a participant-chosen community location to reduce barriers to participation. They met at baseline, 1 ½, 3, 6, 9, and 12 months for Health Coach sessions to help set lifestyle goals. Home visits allowed for more involvement from all family members within the household, as encouraged by the Health Coach. The Health Coach followed up by phone at 2 weeks, 4 ½, 7 ½ and 10 ½ months and as needed over the 12-month intervention. These follow-ups allowed discussion of successes or difficulties, problem-solving, help with resource needs, and provided motivational support. Families were encouraged to engage as many family members as possible on the follow-up phone calls by utilizing the speakerphone option on their devices.

All Health Coach visits were based on MI. MI is a behavioral counseling approach designed to help people identify motivations for change, establish goals relevant to their values and motivations, and increase self-efficacy for achieving those goals. MI addresses the challenge of keeping families engaged by focusing on the family's specific challenges and environment. MI, which is based on social-cognitive theory (self-efficacy), self-determination theory and the empowerment paradigm, uses four techniques to support change: 1) expression of empathy, 2) development of a discrepancy (enhance participant

awareness of inconsistencies between behavior and values), 3) rolling with resistance (acknowledging ambivalence as part of the change process), and 4) supporting client self-efficacy (expression of the possibility of participant change and reinforcement of participant's ability to choose). Health Coaches were trained on MI-based communication skills specific to goal setting and actions related to increasing fruit and vegetable consumption, reducing sugar-sweetened beverage consumption, increasing sleep, reducing stress, and reducing screen time for promoting healthy weights in adults and children. To maintain fidelity, all Health Coach sessions were taped unless the Index Adult explicitly stated they did not wish for the sessions to be taped. From the taped sessions, 20% of sessions were scored using the OnePass coding system. For further validity, 20% of those initially scored by the OnePass coding system were scored again by a second reviewer.

Following initial goal setting through MI, the Health Coach, with assistance from the Community Resource Specialist, linked participants to community resources to meet needs that would otherwise present barriers to goal attainment. We utilized our Community Partners to break these barriers. Two examples of this were the fresh food boxes and gym memberships provided to the Health Coach group. If families chose "Eating More Fruits and Vegetables" as their goal or expressed interest in needing more healthy food for their families, we provided fresh and canned fruits and vegetables during the first 6 months (2 servings/person/day) of the intervention. These food boxes were provided through a local food pantry network and their volunteers. Information regarding sustainable sources of healthy foods through the pantry network and its affiliates was also distributed to participants. Families that chose "Physical Activity" are linked to goal-appropriate resources, such as the low or no cost programs offered by Parks and Recreation or a 4-month free membership to partner YMCA's for all members of the household. Health Coaches followed-up with families to gauge resource utilization and encourage appropriate use of these services. In addition to the specified resources, the Health Coach group also received identical newsletters as the Education Only group.

7.1. Control (Education Only group)

Participants in the Education Only group received the "We Can" family nutrition and activity booklets and quarterly 4-page newsletters containing children's games, physical activity ideas, healthy recipes, and information on community events. Each newsletter also included a raffle in which participants could fill out an updated contact slip with their information and return to the study staff for a chance to win a gift card to a local retail store. The newsletters were distributed in both English and Spanish based on the family's language preference. The Education Only group also received an initial resource screen and follow-up phone call using the Community Resource Specialist's screening questionnaire (APPENDIX #) and referrals to appropriate basic-needs resources. This was repeated at 6 months. These resources were not related to physical activity and nutrition unless specifically requested by the Index Adult, with the exception of food pantries, SNAP and WIC for those who indicated food insecurity.

8. Measures

Body measurements and questionnaires were administered by Data Collectors at baseline, 6-month, 12-month, and 18-month visits to address primary outcomes. Blood pressure measurements are taken at least 30 minutes after arrival. Measurements were taken in a rotating order, separating them with another sort of measurement (i.e. taking weight measurement #1, then height measurement #1, then weight measurement #2, etc.) to limit repeated mistakes. A mistake is more likely to be caught if

measurements are separated by measurement of something else. Our general policy was that results were not be said out loud or given to the participants unless they specifically ask for them. If a participant asked for a result, it was be provided to them in values or units that are understandable (i.e., converting kilograms to pounds). Accelerometer data was collected only at baseline and 12-months to account for seasonality, and this data was not relayed back to the participants.

8.1. Body measurements

For BMI-related outcomes, height and weight were measured via standardized protocols. All measurements were taken twice. A third measurement was taken if the first two values differed by more than 1.0 cm for height and 0.3 kg for weight. Height was taken on a Shorrboard stadiometer. All hair accessories were removed, and hair was taken out from buns/braids/corn rolls/etc. (or compressed if not possible and noted). Participants stood in bare feet or socks with their heels of both feet together. The position of the heels, the buttocks, shoulder blades, and the back of the head contacted the vertical backboard (Figure?). Depending on the overall body conformation of the individual, all points may not have touched. In such a case, the participant's trunk was vertical above the hip, and the arms and shoulders were relaxed. Their head was positioned in the Frankfurt horizontal plane. The head is in the Frankfurt horizontal plane when the line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. The participant was asked to take a deep breath and hold it, and then the headboard firmly on top of the head with sufficient pressure to compress the hair. The measurement was recorded to the last completed 0.1 cm.

Weight was measured using a calibrated digital scale set on a level surface. Research staff made sure that the scale was level by adjusting the feet as needed to ensure that the bubble is centered in the circle. The display was held by the Data Collector or set on a flat surface in a way that results were not displayed to participants or other people in the room. It was checked to be sure the scale was properly zeroed before proceeding. Weight was measured while the participant was wearing normal street clothes and had removed any heavy clothing and accessories and shoes. After making sure the participant was centered on the scale, standing still, with both feet fully on the scale, the participant's weight was recorded to the last completed 0.1 kg.

As indicators of health, waist circumference and blood pressure were also taken on the Index Adult and Primary Food Preparer. Similar to height and weight measurements, waist circumference was taken twice, and a third measurement was obtained if the two prior measurements differed by 0.1 cm. Waist circumference was measured using a Gulick tape measure so it would ensure the same amount of tension is placed on the tape measure each time a measurement is taken. Data Collectors began by locating the iliac crest on one side of the participant's hip and drew a horizontal line just above the uppermost border of the right ilium with a water-soluble marker and then crossed the line to indicate the midaxillary line of the body. These markings were repeated on the other side of the participant's body. The participant was to be standing with a relaxed, natural posture with feet close together and shoulders slightly rounded. The Data Collector, standing on the participant's side, placed the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk. The tape contacted the skin of the participant around the entire waist but did not compress the skin, and the participant's waist circumference to the last completed 0.1 cm was recorded.

Blood pressure is the only measurement that needed to be taken once, unless a concerning result was obtained during this measurement. Blood pressure was measured with either an Omron Automatic

Blood Pressure Monitor (if the participant has an arm circumference between 9 and 17 inches) or a Life Source Extra Large Arm Automatic Blood Pressure Monitor (if the participant has an arm circumference between 16.5 and 23.5 inches). Before taking the blood pressure measurement, the Data Collector waited 30 minutes after arriving to observe no eating, smoking, or exercise took place prior to the reading. The participant was asked to sit quietly for 15 minutes prior to the measurement. The participant removed clothing from the left arm, and the Data Collector placed the correctly sized arm cuff on the participant. The research staff locate the brachial artery on the inside of the upper arm, 1 inch above the elbow, using their index and middle fingers, and then placed the left arm through the cuff loop with the bottom of the cuff at the appropriate height above the crease of the elbow for the monitor. The participant was sitting in a chair with both feet flat on the floor, and resting their relaxed left arm on a table, with their palm upwards. Any concerning values were checked against the Blood Pressure Alert Card, and the Data Collector proceeded as instructed for the given values. If additional measurement was needed, they waited 5-10 minutes before obtaining the next measurement.

8.2. Accelerometer measurements

Accelerometers, ActiGraph GT9X Link, were placed on the non-dominant wrist of the Index Adult and Index Child during baseline and 12-month data collection visits. The participants were instructed to wear the accelerometers continuously for one week. The accelerometers are waterproof and thus did not need to be removed for any reason. After the participants wore the monitors for 7 days, they both (if the Index Child is between the ages of 10 and 12 years) completed a questionnaire (Global Physical Activity Questionnaire for the Index Adult and the Physical Activity Questionnaire for Children for the Index Child) via interview with the Data Collector over the phone. These questionnaires assessed level of physical activity during the same time the monitor is worn, so that the accelerometer data can be compared to the self-reported data.

8.3. Questionnaire measurements

Index Adults are assessed on dietary intake and physical activity via questionnaires. For dietary intake, validated food-frequency questions are administered to monitor intake of fruits, vegetables, and fats (NHIS 2000), sweetened drinks (NHIS 2005), and fast food (EAT study). Physical activity questionnaires include the Global Physical Activity Questionnaire (GPAQ), which provide contextual data to complement accelerometer data and provide information as to where activity is taking place (i.e., domains). The GPAQ will be calibrated with the accelerometer to improve data accuracy in a one-week post-data collection phone visit. Other data is collected, including demographic information, income and food insecurity information, medication usage and dose changes, health history information, substance use, depression screen, and related questions.

Index Children are assessed on dietary intake, physical activity, and screen time. These questionnaires are given to the Index Adults, and they answer the questions as proxy for the children. The Family Nutrition and Physical Activity tool (FNPA) is used, which is a child environmental measure developed in partnership with the American Dietetic Association to characterize behaviors related to childhood obesity. Validation shows a 1-point change is associated with a 0.1 change in BMI z-score, and the score correlates with cardiovascular risk indices. It measures changes emphasized by our intervention including decreasing sweetened beverages, sweet snacks, fast food and TV, and increasing family meals, family physical activity, and fruits and vegetables. The scale allows us to compare families who choose different goals and resources. Additional validated parent questionnaires were used to

assess child screen time, NCI quantitative FV screener and other dietary measures including sugar-sweetened beverages.

The Primary Food Preparer (PFP) of the household (who may be the Index Adult or a different household member) completes a validated survey on the availability of fruits and vegetables in the house and a questionnaire on how often the family eats together inside and outside the home or brings in take-out food. If the PFP is not the Index Adult they complete the same dietary measures as the Index Adult. Other exploratory measures include collecting BMI on the non-Index Adult PFP and other children residing within the household.

9. Data Analysis Plan

The trial design includes three factors: 1) two treatment groups (control, intervention), 2) four time points (0, 6, 12, and 18), and 3) two age groups (adult, child). Each variable will be summarized by descriptive statistics, including mean, standard deviation and quartile at each time point (separately by treatment and age groups). Index Adults and Index Children will be analyzed separately. Outcomes have repeated measures at multiple time-points. The primary analysis compares the change in primary outcomes from baseline to 12 months between the treatment groups to gauge the efficacy of the intervention. The secondary analysis compares both the 6- and 18-month average change from baseline between the two treatment groups to assess short-term effect and longer-term sustainability. The analysis will be based on intention-to-treat and use two-sided t-test for the primary outcomes with multiple imputation to account for missing values. Multiple imputation models will incorporate 6-month values when available. Linear mixed models for repeated measures will be used for other analysis using multiple time points.

9.1. Power

Power calculations were based on data from the pilot intervention and information culled from related trials. See Table

Table 6. Power calculation	Standard deviations	Difference	80% power[a]	Assuming 30% dropout	Source
Adults BMI change	Intervention 2.29[b] Control 2.28	1 kg/m^2	65 per group	92 per group	Wadden (2011)[136]
Adult Accelerometer	Intervention 101.9[c] Control 77.7	35-minutes	82 per group	117 per group	Napolitano (2010)[137]
Children Accelerometer	59.4 for both[d]	30-minute	50 per group	71 per group	Robertson (2011)[138]
FNPA	5.1 for both[e]	2 points	81 per group	116 per group	Ihmels (2009)[119]

[a] Using a two-sided 0.05-level two-sample t-test
[b] Pilot data at 6 months showed a SD 1.98 – We used Wadden's numbers to be conservative
[c] The intervention group had baseline and 12-month SD's of 44.2 and 59.6, while the control group had SD of 42.5 and 44.6. No information was available on the SD of the baseline-to-12-month change. Taking the most conservative approach, we computed the largest possible pre-post SD and found the largest possible baseline-12 month SD's (101.9 intervention, 77.7 control)
[d] Table 1 reported baseline-to-9 months CI's. From these, we computed a 0-9 month SD of 59.4 to use for the 0-12 month change
[e] For those with income <$25,000. Our pilot showed a similar number of SD 5.4 for change at 6 months

Based on these power calculations, a target of 260 families was to be recruited to account for dropout prior to randomization, following randomization, and throughout all timepoints of the intervention.